OVERVIEW OF TOBACCO PRODUCT MANUFACTURING PRACTICE (*TPMP*) PROPOSED REGULATION

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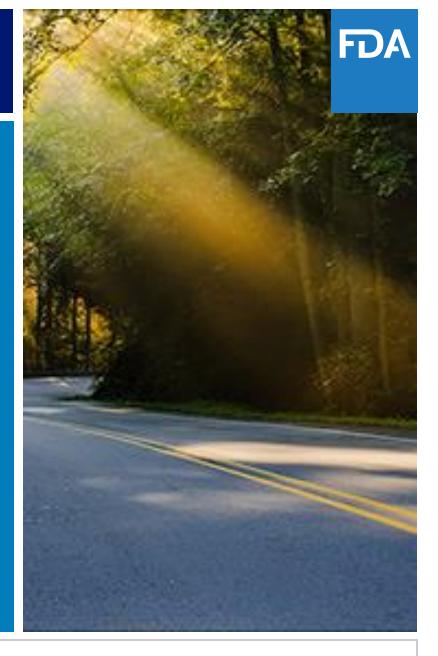
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- This presentation and the attached briefing document contain information prepared by the Food and Drug Administration (FDA) for the panel members of the Tobacco Product Scientific Advisory Committee (TPSAC) on the proposed regulation titled "Requirements for Tobacco Product Manufacturing Practice" (TPMP).
- This presentation and the briefing package may not include all issues relevant to TPSAC's consideration of the proposed regulation.
- It is intended to focus on issues identified by FDA for discussion by TPSAC.
- The information in these materials is not a formal dissemination of information by FDA and does not represent Agency position or policy.
- The information is provided to TPSAC to aid the Committee in its evaluation of the proposed regulation.

Overview
Objectives
Protect Public Health
Compliance with FD&C Act
Scope
Framework
Provisions of Proposed Rule
Topics for Discussion

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OVERVIEW



TPMP is a **foundational rule** that will help protect public health and assist with CTP's authorities, including:

- Premarket review
- Tobacco product standards

OBJECTIVES



TPMP ≠ tobacco product is safe

 Minimize or prevent product problems and health issues not normally associated with use of tobacco product

Statutory objectives:

- Protect public health
- Tobacco products are in compliance with chapter IX of FD&C Act

PROTECT PUBLIC HEALTH



Minimize or prevent and investigate product problems and health issues not normally associated with use of tobacco product

Ensure tobacco products are manufactured to conform to established specifications

Identify and investigate nonconforming tobacco products

Prevent contamination of tobacco products

COMPLIANCE WITH FD&C ACT



Modifications to new and pre-existing tobacco products Other provisions of FD&C Act

- Listing, testing, and reporting of ingredients and additives
- Labels, labeling, and packaging

Establish tracing of all components or parts, ingredients, additives, and materials, as well as each batch of distributed finished or bulk tobacco product

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Adulteration and Misbranding

SCOPE



Finished tobacco product manufacturers

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Bulk tobacco product manufacturers

- Specification developers
- Contract manufacturers
- Repackagers/relabelers

FRAMEWORK



Umbrella approach (flexible requirements)

Manufacturers must comply with requirements applicable to their operations

Small Tobacco Product Manufacturers

- Effective Date: 2-years
- Compliance Date for small tobacco product manufacturers: 4 additional years after 2-year effective date = total 6 years (as required by FD&C Act)
- Petitions for Exemptions and Variances

PROVISIONS OF PROPOSED RULE



| Subpart | Sections | |
|------------------------------------|---|---|
| Management System Requirements | Organization and Personnel Corrective & preventive actions | Tobacco product complaints |
| Buildings, Facilities, & Equipment | Personnel practices Equipment | Buildings, facilities & grounds Environmental controls |
| Design & Development Controls | Design & development activities | Master manufacturing record |
| Process Controls | Purchasing controls Production processes & controls Production record Nonconforming tobacco product Reprocessing & rework | Acceptance activities Laboratory controls Sampling Returned tobacco product |
| Packaging & Labeling Controls | Packaging & labeling controls Manufacturing code | Repackaging & relabeling Warning plans |
| Handling, Storage, & Distribution | Handling & storage | Distribution |
| Recordkeeping & Document Controls | Recordkeeping & document control requirements | |
| Exemptions & Variances | Exemptions & variances Petition for an exemption or variance Referral to TPSAC | Petition determination Hearing |

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TOPICS FOR DISCUSSION



- The proposed scope of the rule covers finished and bulk tobacco product manufacturers, including specification developers. Does the committee have any recommendations on the scope, including expanding the scope?
- Does the committee have any recommendations or comments on the "umbrella" approach that proposes requirements in flexible terms to enable manufacturers who are subject to the rule to establish procedures that are appropriate for their specific products and operations?
- Does the committee have any recommendations on the product specifications that FDA proposes to require in the MMR?
- Does the committee have any recommendations on the proposed design and development activities and risk management process to control risks associated with finished and bulk tobacco product and its production processes, packing, and storage?
- Does the committee have any additional recommendations on the requirements of the proposed rule?